Signature

PTO/SB/21 (05-03) Approved for use through 04/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. **Application Number** RADEMARY 10/689,225 TRANSMITTAL Filing Date October 20, 2003 **FORM** First Named Inventor **GH Cantor** Art Unit not yet assigned (to be used for all correspondence after initial filing) Examiner Name not yet assigned Attorney Docket Number 01274.US1 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication X Fee Transmittal Form Drawing(s) to Group Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences **Appeal Communication to Group** Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a **Proprietary Information** After Final **Provisional Application** Power of Attorney, Revocation Status Letter Affidavits/declaration(s) **Change of Correspondence Address** Other Enclosure(s) (please Terminal Disclaimer **Extension of Time Request** Identify below): **Executed Declaration** Request for Refund Express Abandonment Request Return Receipt Postcard CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Pharmacia & Upjohn Company Edward F. Rehberg, 34,703 Individual name Signature Date CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. Typed or printed name

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

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Complete if Known					
Application Number	10/689,225				
Filing Date	October 20, 2003				
First Named Inventor	GH Cantor				
Examiner Name	not yet assigned				
Art Unit	not yet assigned				
Attorney Docket No.	01274.US1				

METHOD OF PAYMENT (check all that app	oly)	FEE CALCULATION (continued)					
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Deposit Account:				Small			
Deposit Account 21-0718		Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
Number	·	1051	130	2051	65	Surcharge - late filing fee or oath	
Deposit Account Pharmacia & Upjohn Company	,	1052	50	2052		Surcharge - late provisional filing fee or cover sheet	
Name The Director is authorized to: (check all that apply)		1053	130	1053	130	Non-English specification	
Charge fee(s) indicated below Credit any overp	ayments	1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
Charge any additional fee(s) or any underpayment of fee		1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.		1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
FEE CALCULATION		1251	110	2251	55	Extension for reply within first month	
1. BASIC FILING FEE		1252	420	2252	210	Extension for reply within second month	
Large Entity Small Entity		1253	950	2253	475	Extension for reply within third month	
Fee Fee Fee Fee Fee Description Fe Code (\$) Code (\$)	e Paid	1254	1,480	2254	740	Extension for reply within fourth month	
1001 770 2001 385 Utility filing fee		1255	2,010	2255	1,005	Extension for reply within fifth month	
1002 340 2002 170 Design filing fee		1401	330	2401	165	Notice of Appeal	
1003 530 2003 265 Plant filing fee		1402	330	2402	165	Filing a brief in support of an appeal	
1004 770 2004 385 Reissue filing fee		1403	290	2403	145	Request for oral hearing	
1005 160 2005 80 Provisional filing fee		1451	1,510	1451	1,510	Petition to institute a public use proceeding	
SUBTOTAL (1) (\$)0.00		1452	110	2452	55	Petition to revive - unavoidable	
2. EXTRA CLAIM FEES FOR UTILITY AND R		1453	1,330	2453	665	Petition to revive - unintentional	
Fee from		1501	1,330	2501	665	Utility issue fee (or reissue)	
	Fee Paid \$0.00	1502	480	2502		Design issue fee	
	\$0.00	1503	640	2503		Plant issue fee	
Claims	\$0.00	1460	130	1460		Petitions to the Commissioner	
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Large Entity Small Entity Fee Fee Fee Fee Fee Description		1806	180	1806		Submission of Information Disclosure Stmt	
Code (\$) Code (\$)		8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1202 18 2202 9 Claims in excess of 20 1201 86 2201 43 Independent claims in exce	ss of 3	1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1203 290 2203 145 Multiple dependent claim, i		1810	770	2810	385	For each additional invention to be	
1204 86 2204 43 ** Reissue independent da over original patent	ims	1801	770	2801	385	examined (37 CFR 1.129(b)) Request for Continued Examination (RCE)	
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**or number previously paid, if greater; For Reissues, see		*Redu	iced by	Basic I	Filing F	ee Paid SUBTOTAL (3) (\$) 0.00)

SUBMITTED BY					(Complete (if applicable))
Name (Print/Type)	Edward F. Rehberg	0.1	Registration No. (Attorney/Agent)	34,703	Telephone	(269) 833-7829
Signature	duant 1	Poliber			Date	8-03-04

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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DECLARATION (37 CFR §1.63) AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD OF USING ANIMAL MODELS TO PREDICT ADVERSE DRUG REACTIONS, Docket No. 01274.US1, the specification of which

- [] is attached hereto.
- [X] was filed on October 20, 2003 as Application Serial No. 10/689,225.
- [] was filed on as PCT International Application No. and was amended under PCT Article 19 on, if applicable.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

GHC

LUNE 4 100-4

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 CFR §1.56(a).

I hereby claim the benefit under 35 USC §119(e) of any United States provisional application(s) listed below:

Application Filing Date

Serial No. (Day/Month/Year)

60/421,950 October 29, 2002

I hereby claim foreign priority benefits under 35 USC §119(a)-(d), or §365(b), of any foreign application(s) for patent or inventor's certificate or §365(a) of any PCT International Application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International Application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application on which priority is claimed:

Application Filing Date Priority Claimed

Serial No. Country (Day/Month/Year) (Yes/No)

I hereby claim the benefit under 35 USC §120, of any United States application(s) or PCT International Application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of 35 USC §112, I acknowledge the duty to disclose material information as defined in 37 CFR §1.56(a), which occurred between the filing date of the prior application and the national or PCT international filing date of this application: CHC

2004 2004

Application Serial No.

Filing Date

Status (Patented, Pending, Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint

[X] the practitioners associated with Customer Number

25533

PATENT AND TRADEMARK OFFICE

[] Thomas A. Wootton (Registration No. 35,004); Lucy X. Yang (Registration No. 40,259); Edward F. Rehberg (Registration No. 34,703); John H. Engelmann (Registration No. 28,075); Austin W. Zhang (Registration No. 48,061); Stephen L. Nesbitt (Registration No. 28,981); Mary J. Hosley (Registration No. 48,324); Jonathan P. O'Brien (Registration No. 50,852); and J. Trevor Lumb (Registration No. 28,567); all registered to practice before the Patent and Trademark Office.

as my attorneys or agents with full power of substitution and revocation to prosecute this application and all divisions and continuations thereof and to transact all business in the Patent and Trademark Office connected therewith and request that all correspondence and telephone communications be directed to the following person at the mailing address and telephone number hereafter given:

Name : Edward F. Rehberg, Attorney

Registration No. : 34,703

Address : Pharmacia & Upjohn Company

Global Intellectual Property

301 Henrietta Street

Kalamazoo, Michigan 49001

Telephone No. : (269) 833-7829 or (269) 833-9500

Telefax No. : (269) 833-8897 or (269) 833-2316

Inventor's Signature	Glem H. Contr	Date June 4, 2004
Post Office Address:	irst inventor: Glenn H. Cantor ewell. Townships 0, Michigan 49008 08540 Citi 4033 East Hillandale, Kalamazon 77 Elm Ridge Ross, Pri	o, Michigan 49008

Inventor's Signature		
Residence: Glayhall,	oint inventor: Martin Geppert Ilford, Essex, United Kingdom IG5 OBG 33 Abbotswood Gardens, Glayhall, Ilford,	Citizenship: Germany Essex, United Kingdom IG5



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As a below-named inventor, I hereby declare that:

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I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD OF USING ANIMAL MODELS TO PREDICT ADVERSE DRUG REACTIONS, Docket No. 01274.US1, the specification of which

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Application Filing Date Priority Claimed
Serial No. Country (Day/Month/Year) (Yes/No)

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: (269) 833-7829 or (269) 833-9500

Telefax No.

: (269) 833-8897 or (269) 833-2316

Inventor's Signature	Date
Full name of sole or first inventor: Glenn H. C Residence: Kalamazoo, Michigan 49008 Post Office Address: 4033 East Hillandale, Ka	Citizenship: USA

Inventor's Signature Martin Gepped Date 27th Feb. 2004

Full name of second joint inventor: Martin Geppert

Residence: Glayhall, Ilford, Essex, United Kingdom IG5 OBG Citizenship: Germany Post Office Address: 33 Abbotswood Gardens, Glayhall, Ilford, Essex, United Kingdom IG5

OBG

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AUG O	5 2004 F REES	RENCES CITE	D BY APPLICANT	1	Docket No.			Serial No. 0/689,225	
				Applicant	GH Cantor	, М Серр	ert		
				Filing Date	October 20	, 2003	Group (not yet ass	signed)
			U.S. PA	ATENT DOCUM	ENTS				
Examiner Initial		Document Number	Date	Name		Class	Subclass	Filing Da	
	AA	5,523,222	June 4, 1996	Page et. al.		435	172.3	Aug 5, 19	994
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	1	T	OTHER PRIOR ART (Inc	cluding Author, Title,	, Date, Pertinent I	Pages, Etc.)			
	AO	Brayton, C., M. Veterinary Path	Justice, and C. A. Montgology 38:1-19	gomery. 2001. Ex	aluating muta	nt mice:	Anatomic pa	ithology.	
	AP		S., J. McWhir, W.A. Rito ine, Nature 380: 64-66	chie, & I. Wilmu	t, 1996. Sheep	Cloned b	y Nuclear T	ransfer fro	m a
	AQ	Q Gavaghan, C. L., E. Holmes, E. Lenz, I. D. Wilson, and J. K. Nicholson. 2000. An NMR-based metabonomic approach to investigate the biochemical consequences of genetic strain differences: application to the C57BL10J and Alpk: ApfCD mouse. FEBS Letters 484:169-174							
	AR	P. Soubrie. 2002 methylphenyl)et selective cortico	imiand, R. Steinberg, M. 2. 4-(2-Chloro-4-methox; hyl]5-methyl-N-(2-proportrophin-releasing factor(s. Journal of Pharmacolo	y-5-methylpheny ynyl)-1,3-thiazol- (1) receptor antag	l)-N-[(1S)-2-c 2-amine hydro gonist. II. Char	yclopropy ochloride acterization	d-1-(3-fluore (SSR125543 on in rodent	o-4- 3A), a pote	nt and

			Atty.	Docket No.	Serial No.
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LIST O		ERENCES CITED BY APPLICANT Use several sheets if necessary)			
			Applicant	GH Cantor, M Gepp	pert
			Filing Date	October 20, 2003	Group (not yet assigned)
	AS	Houdebine, L.M.; Transgenic Animal G	eneration and Us	e, Harwood Academic I	Press, 1997
	AT	Robertson, D. G., M. D. Reily, J. C. Line as a tool for rapid throughput in vivo tox B. Mattes, and W. F. Greenlee (ed.), Cor	icity screening, p	p. 583-626. In J. P. Van	den Heuvel, G. H. Perdew, W.
	AU	Robertson, D. G., E. M. Urda, M. A. Breider, and R. M. Gauthier. 1998. Evaluation of hepatic toxicity of seven-day repeated-dose glutathione-depleting regimens in rats. Toxicology Methods 8:233-244			
	AV	Sundberg, J.P., and D. Boggess. 2000. S Boca Raton, Florida.	ystematic approa	ach to evaluation of mou	ise mutations, 1 ed. CRC Press
	AW	Tymms, M.J., and I. Kola. 2001. Gene K	Knockout Protoco	ols. Humana Press, Tota	wa, New Jersey.
	AX	Ward, J. M., J.F.Mahler, R.R. Maronpot ed. Iowa State University Press, Ames, I		erg. 2000. Pathology of	genetically engineered mice, 1
	AY	Warren, T. K., K. A. Mitchell, and B. P. (TCDD) suppresses the humoral and cel cytolytic activity in the lung. Toxicologi	l-mediated immu	ne responses to influenz	
	AZ	Wilmut, I., A.E. Schnieke, J. McWhir, A Fetal and Adult Mammalian Cells. Natur		-	able Offspring Derived From
Examiner			Date Consider	ed	